IS 12375-7 (1998): Implants for Surgery - Partial and Total Hip Joint Prostheses, Part 7: Endurance Performance of Stemmed Femoral Components without Application of Torsion [MHD 2: Orthopaedic Instruments, Implants and Accessories]

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IS 12375 (Part 7) : 1998
ISO 7206-7 : 1993

भारतीय मानक

शल्य चिकित्सा के लिए अन्तर्रोपण — आंशिक और संपूर्ण कूल्हे पर के जोड़

भाग 7 ऐंठन रहित अनुप्रयोग के डन्डीनुमा फेमोरेल अवयवों की सह्यता कार्यकारिता

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL HIP JOINT PROSTHESES

PART 7 ENDURANCE PERFORMANCE OF STEMMED FEMORAL COMPONENTS WITHOUT APPLICATION OF TORSION

ICS 11.040.40

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

November 1998

Price Group 1

NATIONAL FOREWORD

This Indian Standard (Part 7) which is identical with ISO 7206-7 : 1993 'Implants for surgery — Partial and total hip joint prostheses — Part 7 : Endurance performance of stemmed femoral components without application of torsion' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of the Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to an International Standard for which Indian Standard also exists. The corresponding Indian Standard which is to be substituted in its place is given below along with its degree of equivalence for edition indicated :

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
7206-3 : 1988	IS 12375 (Part 3) : 1993 Implants for surgery — Partial and total hip joint prostheses : Part 3 Determination of endurance properties of stemmed femoral components with application of torsion	Identical

This standard has been issued in 9 parts. Other parts of this standard are:

Part 1 Classification, designation of dimensions and requirements

Part 2 Bearing surfaces made of metallic and plastic materials

Part 3 Determination of endurance properties of stemmed femoral components without application of torsion

Part 4 Determination of endurance properties of stemmed femoral components with application of torsion

Part 5 Determination of resistance to static load of head and neck region of stemmed femoral components

Part 6 Determination of endurance properties of head and neck region of stemmed femoral components

Part 8 Endurance performance of stemmed femoral components with application of torsion

Part 9 Detremination of resistance to torque of head fixation of stemmed femoral components

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

IMPLANTS FOR SURGERY — PARTIAL AND TOTAL HIP JOINT PROSTHESES

PART 7 ENDURANCE PERFORMANCE OF STEMMED FEMORAL COMPONENTS WITHOUT APPLICATION OF TORSION

1 Scope

This part of ISO 7206 specifies the endurance performance of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement as determined under specified laboratory conditions by a method that does not include the application of torsion.

This part of ISO 7206 does not apply to the following:

a) prostheses for special clinical cases;

b) prostheses in which the stem is curved out of the plane of the axis of the neck.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 7206. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7206 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7206-3:1988, *Implants for surgery — Partial and total hip joint prostheses — Part 3: Determination of endurance properties of stemmed femoral components without application of torsion.*

3 Endurance performance

When tested as described in ISO 7206-3, the femoral component shall not fracture during 5×10^6 cycles of application of a cyclic load of 3 kN with a minimum load of 300 N and a maximum load of 3,3 kN. Neither shall the test have been terminated before completion of the loading regime (see subclause 7.8 of ISO 7206-3:1988) for reasons other than loosening of the specimen in the embedding medium.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards : Monthly Additions'.

This Indian Standard has been developed from Doc : No. MHD 2 (2707).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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